STATE OF MAINE

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE FOR COMMERCIAL NUCLEAR PHARMACY OR RADIOPHARMACY USE

INSTRUCTIONS: *This application complies with the license requirements of Section C of the State of Maine Rules Relating to Radiation Protection (SMRRRP). Complete items 1 through 12. Supplemental sheets may be needed for items 5 through 11. Mail the completed application to:* **Radiation Control Program, 11 State House Station, Augusta, Maine, 04333. Telephone: (207) 287-5676.**

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1. THIS IS AN APPLICATION FOR (check one)

	NEW LICENSE	LICENSE NUMBER (leave blank)
	RENEWAL of license number >	
	AMENDMENT of license number >	

2. NAME AND MAILING ADDRESS OF APPLICANT	**3. ADDRESS(ES) WHERE MATERIAL WILL BE USED AND/OR STORED.**
PHONE:	PHONE:

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

NAME:_____ PHONE:_____ EMAIL:

For items 5 through 11, the requested information may be submitted on standard size paper. Answer all items. For any that do not apply, answer by giving the item number with "not applicable" after it.

5. RADIOACTIVE MATERIAL:

A: Radioactive Material for commercial nuclear pharmacy or radiopharmacy use: Please place an "X" next to all the disciplines you wish to be licensed for.

Radioactive Material listed in:	X	Chemical and/or physical form	Max. possession limits:(mCi)
Any byproduct materials with Atomic No. 1-83, except Mo^{99}, $Tc^{99}m$, I^{131}, Xe^{133}			
Molybdenum-99 (Mo^{99})			
Technetium-99m ($Tc^{99}m$)			
Iodine-131 ($I^{131)}$			
Xenon-133 (Xe^{133})			
Any byproduct materials in a Brachytherapy Source as listed in G.400			
Any byproduct material in a sealed source for diagnosis as listed in G.500			
Any byproduct material listed in C.6.F.			
Any byproduct material authorized under G.20			
Depleted uranium			
Other (please specify)			

If Financial Assurance is required then ***Evidence of Financial Assurance must be provided***

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED:

For Radiopharmaceuticals

	We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to the SMRRRP Part C.
	Description of all licensed material to be distributed or redistributed is provided.

For Generators

	We confirm that the generators will be obtained from a manufacturer licensed pursuant to SMRRRP Part C.
	We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For Redistribution of Used Generators

	Descriptionof the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport is provided.
	We confirm that the manufacturer's packaging and labeling will not be altered.
	We confirm that the generator will not be distributed beyond the expiration date shown on the generator label.
	We confirm that the redistributed generator will be accompanied by the manufacturer supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.
	We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

For Redistribution of Sealed Sources – for Brachytherapy or Diagnosis

	We confirm that sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to SMRRRP Part C.
	We confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer supplied package insert, leaflet, brochure or other document that provides radiation safety instructions for handling and storing the sources.

For Redistribution of Calibration and Reference Sealed Sources

	We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to SMRRRP Part C.
	We confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer supplied calibration certificate and the leaflet, brochure or other document that provides radiation safety instructions for handling and storing the sources.

For Redistribution of Prepackaged Units for *In Vitro* Tests

	We confirm that prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to SMRRRP Part C.

For Redistribution to General Licensees

	We confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way.
	We confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer supplied package insert, leaflet, brochure that provides radiation safety instructions for general licensees.

For Radiopharmaceutical Preparation, we will perform

	Compounding of Iodine-131 capsules
	Radioiodination
	Technetium-99m kit preparation
	Other (please specify)

Supply specific information concerning the uses of

	Sealed sources for reference and calibration
	Depleted uranium

We will provide customers the following radiation protection services involving licensed material

	Leak testing
	Instrument calibration
	Other, specify.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE: On a separate sheet, list the names of all individuals who will use or directly supervise use of the radioactive material(s) listed on the license. Provide training and experience documentation for each individual as appropriate. (NOTE: if users are already approved on another license, please submit a copy of the license they are on. Remember, if they have not been listed on a license within the past 5 years, evidence of refresher training must be submitted).

7.1 Management Structure Provide the following:

	An organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the radiation safety officer is provided.

7.2 Radiation Safety Officer (RSO) Provide the following:

	A copy of the license that authorized the uses requested and on which the individual was specifically named as RSO, an Authorized Nuclear Pharmacist, or an Authorized User.
	OR a description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Refer to Appendix G of NUREG-1556, Vol. 13 (Sept 1999) for guidance.

7.3 Authorized Nuclear Pharmacist (ANP) Provide the following:

	A copy of the State Pharmacy license or registration for the pharmacist.

	A copy of the license on which the individual was specifically named as an ANP;
	OR a copy of the permit maintained by a licensee of broad scope that identifies the individual as an ANP;
	OR a copy of a the pharmacist's certification (s) from the radiopharmacy board(s) approved by the NRC;
	OR a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience; and written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy. Refer to Appendix G of NUREG-1556, Vol. 13 (Sept 1999) for guidance.

	Description of the recentness of training, if necessary.

7.4 Authorized User (AU) Identify types, quantities, and proposed uses of licensed material and provide the following:

	A copy of the license on which the individual was specifically listed as an AU for the types, quantities, and proposed uses of licensed material;
	OR a copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials;
	OR a description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed material. Refer to Appendix G of NUREG-1556, Vol. 13 (Sept 1999) for guidance.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:

8.1 Occupationally Exposed and Ancilliary Personnel

	We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualification of instructors; method of training; method of assessing the success of the training; and the frequency of training and refresher training.

8.2 Personnel involved in Hazardous Materials Package Preparation and Transport

	We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements of the SMRRRP Part L, 49 CFR 172.700, 49 CFR 172.702 and 49 CFR 172.704, as applicable.

8.3 Supervised Individuals Preparing Radiopharmaceuticals

	We have developed and will implement and maintain written procedures for training personnel involved in the preparation of radiopharmaceuticals, including: topics covered; qualification of instructors; method of training; method of assessing the success of the training; and the frequency of training and refresher training.

9. FACILITIES AND EQUIPMENT: Provide a description of the facilities and equipment to be made available at each location where radioactive material is to be used, a diagram of the entire facility, and identification of activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated. Include the following information:

	Copy of the pharmacy registration or license issued by the State Board of Pharmacy as a pharmacy.
	Diagram of the facilities and equipment.
	Diagram is sufficient in detail to indicate locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.
	Description of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage.
	Description of the ventilation systems, including glove boxes or fume hoods, with pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of radioactive materials with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions.
	Verification that ventilation systems ensure that effluents are within and the ALARA considerations for air emissions established under SMRRRP Part D as applicable.

10.RADIATION SAFETY PROGRAM:

10.1 Audit Program

	We will conduct an annual audit to review the content and implementation of the radiation protection program.

10.2 Survey Instruments

	We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J to NUREG-1556, Vol. 13 (Sept 1999);
	OR We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 13, (Sept 1999), and instruments will be calibrated by persons authorized by the Agency, the NRC, an Agreement State, or a Licensing State to perform that service;
	OR Description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment is submitted.

10.3 Material Receipt and Accountability

	We have developed and will implement and maintain, written procedures for safely opening packages that meet the requirements of SMRRRP Part D as applicable.
	We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed six months.
	We have developed and will implement and maintain, written procedures for licensed material accountability and control to ensure that: license possessions are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; and records of receipt, transfer, and disposal of licensed material are maintained.

10.4 Occupational Dose

	We have developed and will implement and maintain, written procedures for monitoring occupational dose that meets the requirements of SMRRRP Part D as applicable.

10.5 Public Dose

	We will ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) (TEDE) in one year from licensed activities and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations..

	We will ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions.

	We will implement procedures to prevent unauthorized access, removal, or use of licensed material.

10.6 Safe Use of Radionuclides and Emergency Procedures

	We have developed and will implement and maintain, written procedures for the safe use of radioactive materials that address: facility and personnel radioactive contamination minimization, detection and control; performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use; and use of protective clothing and equipment by personnel that meet the requirements of SMRRRP Parts C, D, and J as applicable.

10.7 Emergency Procedures

	We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including; lost, stolen, or missing licensed material; exposures to personnel and the public in excess of Agency regulatory limits; releases of licensed materials in effluents and the sanitary sewer in excess of Agency regulatory limits; excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas; radioactive spills and contamination; fires, explosions, and other disasters with the potential for the loss of containment of licensed materials; and routine contacts with local fire departments that meet the requirements of SMRRRP Parts C and D as applicable.

10.8 Surveys

	We have developed and will implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements of SMRRRP Parts C and Part D as applicable.

10.9 Dosage Measurement Systems

	Description of the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, and photon-emitting radioactive drugs is submitted.

	We have developed and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests for alpha-, beta-, and photon-emitting radioactive drugs, as applicable, that meet the requirements in SMRRRP Part C.

	If applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers is submitted.
	OR a means for insuring the accuracy of beta-correction factors supplied by the instrument manufacturer or other entity is submitted.

10.10 Transportation

	We will develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with Agency/NRC/AS and DOT regulations.

10.11 Minimization of Contamination

	Description of how facility design and procedures for operation will minimize , to the extent practicable, contamination of thr facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste is provided.

10.12 Radioactive Drug labeling for Distribution

	Description of all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the "transport radiation shield" or the container used to hold the radioactive drug) is submitted. Provide sample labels if available.

	We will affix the required labels to all "transport radiation shields" and each container used to hold radioactive drugs.

10.13 Radioactive Drug Shielding for Distribution On a separate sheet provide the following for each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

	The radionuclide and the maximum activity for each type of container (e.g., vial, syringe).

	Description of the type and thickness of the "transport radiation shield" provided for each type of container.

	The maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity. Description of the type and thickness of the "transport radiation shield" provided for each type of container.

10.14 Leak Tests

	We have developed and will implement and maintain written procedures for leak testing that meet the requirements in SMRRRP Parts C and D as applicable.

11. WASTE MANAGEMENT:

11.1 Pharmacy-Generated Radioactive Waste

	We have developed and will implement and maintain written procedures for waste management that meet the requirements of SMRRRP Parts C and D as applicable

11.2 Returned Waste From Customers

	We have developed and will implement and maintain written procedures for customer return of pharmacy supplied syringes and vials and their contents, to specify that: only pharmacy supplied syringes and vials and their contents may be returned to the pharmacy; instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy; and instructions will be provided to pharmacy staff for the pick-up, receipt and disposal of the radioactive waste that meet the requirements in SMRRRP Parts C, D, and L, as applicable.

12. CERTIFICATION: The applicant and any official executing this certificate on behalf of the applicant named in item 2, certify that this application is prepared in conformity with the State of Maine Rules Relating to Radiation Protection and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

DATE:_____ SIGNATURE OF APPLICANT:_____

TITLE:_____ TYPED/PRINTED NAME:_____